

Food and Drug Administration, HHS

§ 522.313a

and exotic animal practice, wildlife management programs, or research.

[79 FR 16185, Mar. 25, 2014]

§ 522.304 Carprofen.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) carprofen.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount.* 2 mg/lb (4.4 mg/kg) body weight once daily or 1 mg/lb (2.2 mg/kg) twice daily, by subcutaneous injection. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(2) *Conditions of use.* For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 26205, May 15, 2003, as amended at 68 FR 34796, June 11, 2003; 68 FR 49351, Aug. 18, 2003. Redesignated at 73 FR 29685, May 22, 2008, as amended at 79 FR 16185, Mar. 25, 2014]

§ 522.311 Cefovecin.

(a) *Specifications.* Each milliliter of constituted solution contains 80 milligrams (mg) cefovecin as the sodium salt.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 3.6 mg/pound (lb) (8 mg/kilograms (kg)) body weight as a single subcutaneous injection. A second subcutaneous injection of 3.6 mg/lb (8 mg/kg) may be administered if response to therapy is not complete.

(ii) *Indications for use.* For the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G).

(2) *Cats*—(i) *Amount.* Administer 3.6 mg/lb (8 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use.* For the treatment of skin infections (wounds and

abscesses) in cats caused by susceptible strains of *Pasteurella multocida*.

[73 FR 29685, May 22, 2008, as amended at 79 FR 16185, Mar. 25, 2014]

§ 522.313 Ceftiofur injectable dosage forms.

§ 522.313a Ceftiofur crystalline free acid.

(a) *Specifications.* The product is a suspension of ceftiofur crystalline free acid.

(1) Each milliliter (mL) contains 100 milligrams (mg) ceftiofur equivalents.

(2) Each mL contains 200 mg ceftiofur equivalents.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Swine.* The formulation described in paragraph (a)(1) of this section is used as follows:

(i) *Amount.* 5.0 mg CE per kilogram (kg) of body weight by intramuscular injection in the postauricular region of the neck.

(ii) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis*. For the control of SRD associated with *A. pleuropneumoniae*, *P. multocida*, *H. parasuis*, and *S. suis* in groups of pigs where SRD has been diagnosed.

(iii) *Limitations.* Following label use as a single treatment, a 14-day pre-slaughter withdrawal period is required.

(2) *Cattle.* The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount.* For subcutaneous (SC) injection in the posterior aspect of the ear where it attaches to the head (base of the ear) in lactating dairy cattle. For SC injection in the middle third of the posterior aspect of the ear or in the base of the ear in beef and non-lactating dairy cattle.

(A) Single-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight as a single injection.

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(B) Two-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight given as two injections in the base of the ear approximately 72 hours apart.

(ii) *Indications for use*—(A) Single-dose regimen: For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef, non-lactating dairy, and lactating dairy cattle. For the control of respiratory disease in beef and non-lactating dairy cattle which are at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni*. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii* in beef, non-lactating dairy, and lactating dairy cattle.

(B) Two-dose regimen: For the treatment of acute metritis (0-to 10-days postpartum) associated with bacterial organisms susceptible to ceftiofur in lactating dairy cattle.

(iii) *Limitations*. Following label use as either a single-dose or 2-dose regimen, a 13-day pre-slaughter withdrawal period is required after the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

(3) *Horses*. The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount*. Two intramuscular injections, 4 days apart, at a dose of 3.0 mg/lb (6.6 mg/kg) body weight.

(ii) *Indications for use*. For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* ssp. *zooepidemicus*.

(iii) *Limitations*. Do not use in horses intended for human consumption.

[68 FR 60296, Oct. 22, 2003, as amended at 69 FR 43892, July 23, 2004. Redesignated and amended at 71 FR 39546, July 13, 2006; 73 FR 58872, Oct. 8, 2008; 75 FR 4692, Jan. 29, 2010; 75 FR 62468, Oct. 12, 2010; 77 FR 26162, May 3, 2012; 79 FR 16185, Mar. 25, 2014]

§ 522.313b Ceftiofur hydrochloride.

(a) *Specifications*. Each milliliter of ceftiofur hydrochloride suspension con-

tains 50 milligrams (mg) ceftiofur equivalents.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.113 of this chapter.

(d) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle and swine for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

(e) *Conditions of use*. (1) *Swine*—(i) *Amount*. 3 to 5 mg per kilogram (/kg) of body weight by intramuscular injection. Treatment should be repeated at 24-hour intervals for a total of 3 consecutive days.

(ii) *Indications for use*. For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella Choleraesuis*, and *Streptococcus suis*.

(iii) *Limitations*. Treated swine must not be slaughtered for 4 days following the last treatment.

(2) *Cattle*—(i) *Amount*. Administer by subcutaneous or intramuscular injection as follows:

(A) For bovine respiratory disease and acute bovine interdigital necrobacillosis: 1.1 to 2.2 mg/kg of body weight at 24-hour intervals for 3 to 5 consecutive days.

(B) For bovine respiratory disease: 2.2 mg/kg of body weight administered twice at a 48 hour interval.

(C) For acute metritis: 2.2 mg/kg of body weight at 24-hour intervals for 5 consecutive days.

(ii) *Indications for use*. For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *P. multocida*, and *Histophilus somni*; acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*; and acute metritis (0 to 14 days post-partum) associated with bacteria susceptible to ceftiofur.